"Work with these reagents will not be published without prior approval by Dr. Gallo;" "Reagents will not be used in comparisons with other viruses."

ORI will show that these restrictions were part of an effort by Dr. Gallo to ensure that Dr. Martin would not be able to advance certain areas of research. Dr. Martin will testify regarding his interactions with Dr. Gallo on this matter. See also Exhibit H-18.

Dr. Gallo also balked at sharing the uninfected cell line with the Pasteur scientists and stated that, if they wanted the cell line, they should get it from CDC. Exhibit H-120. Dr. Gallo further stated that he did not think the uninfected cell line would be useful for a comparison of LAV and HTLV-IIIB and the uninfected cell line was not available because the LTCB was still characterizing it. Although Dr. Gallo stated that it was the United States government's position that the cell line should not be distributed, the guidelines clearly give Dr. Gallo the ability to provide the cell line to the French researchers. Ultimately, it was not until October of 1984, many months after publication of the Science papers, that the Pasteur scientists received the H9 cell line.

ORI will show that Dr. Gallo's refusal to provide the uninfected cell line to some scientists was consistent with his actions with other valuable reagents. For example, Jay A. Levy, M.D. requested that Dr. Gallo send him rabbit antiserum to HTLV-III to check the virus isolates that Dr. Levy had identified.

Exhibit H-82. Dr. Gallo weighed how to respond to Dr. Levy's request[40] and ultimately did not send Dr. Levy the sera necessary to determine if he had unique isolates. See also, Exhibit H4 at 167.

(3) Extraordinary conditions placed on the CDC: 8, 9

[41][42]Although CDC had specifically requested the uninfected cell line and had executed agreements in May 1984 providing for its release[43], Dr. Gallo did not provide the uninfected cell line to CDC until June 1984, i.e., Dr. Gallo waited over a month to respond to the CDC's request for uninfected H9. See Exhibit H-92.

When Dr. Gallo finally provided materials to CDC, --- a sister PHS facility --- the agreement included seven restrictions. Like the agreement tailor-made for Dr. Martin, the CDC agreement was tailor-made for that facility. The two additional restrictions in the CDC form provided that (1) work with HTLV-III will not be published without prior approval by Gallo and (2) reagents will not be used in comparisons with other viruses. But Gallo imposed an even more obnoxious condition on CDC, i.e., not only did he tell the CDC scientists what they

---

[40] See handwritten note on Exhibit H-82.

[41] Drs. Curran, Mason, Francis, Murphy, Cabradilla, Dowdle and Kalyanaraman will provide testimony on these requests.

[42] Testimony to be provided by Drs. Curran, Mason, Francis, Murphy, and Cabardilla.

[43] See Exhibit H-94.

could not do with the infected cell line; he specified to CDC the only kinds of research it could do: "They (the reagents) will only be used for seropidemiologic studies and blood bank assays."

(Nor was this the only incident when Dr. Gallo restricted a recipient scientist to particular kinds of experiments. A specially-made form was developed for Dr. James Mullins, significantly limiting what he was permitted to do with the H9 cell line.)

The occasion on which the CDC scientists were made to sign the severely restrictive form (notably, the CDC scientists were not provided a copy of the form) was memorialized in a memorandum prepared by Dr. Fred Murphy, after his return from the LTCB. Exhibit H-97. According to the Murphy memorandum, the meeting in Dr. Gallo's office "was a tense moment, fraught with the possibility of non-delivery." The CDC scientists reportedly emphasized to Gallo their concerns for the public good, but "... it became clear that comparison of his HTLV-III prototype with the French prototype LAV occupied a separate niche ... since CDC had lab competency which could become competitive, a restriction would have to be placed on the use made of his infected cells."

B. Standards for the Sharing of Research Resources

ORI will prove that it was and is a commonly accepted practice within the scientific community that when a researcher has published research on a specific cell line, it is incumbent on the researcher to make the cell line freely available. These standards are reflected in numerous policies and publications.

The National Academy of Sciences (the "Academy") specifically recognizes that: "After publication, scientists expect that data and other research materials will be shared upon request... [S]cientists should not deny requests for primary data because of professional jealousy." The Academy also acknowledged that proprietary interests of the scientist can be protected by the filing of a patent.[44] Because Dr. Gallo had already protected whatever financial interests he might have had by filing a patent application, he had no basis for withholding the reagents from other researchers.

In 1989, the Institute of Medicine, Division of Health Sciences Policy, produced a Report of a study by a committee on the Responsible Conduct of Research. Exhibit H-270. The panel recognized that "authors of published work have a traditional obligation to aid scientists interested in independent replication [including] . . . access to the methods and reagents necessary for reproduction." The panel further noted that this obligation is usually "an unstated assumption in academic research." Exhibit H-270 at 72. (emphasis added) The panel suggested that investigators have a responsibility to share with qualified peers attempting independent reproduction of the work when the reagents are not generally available. Many journals including Science and Cell have incorporated this tradition as a condition of publication. The panel noted that reagents should

---

[44] See Exhibit H-271 at 12.

be made available shortly after publication. Exhibit H-270 at 73. See also Exhibit H-177 at 24.

ORI will present numerous witnesses that will testify that such a standard existed in the scientific community in 1984 and exists now.[45] The Richards Panel chastised Dr. Gallo's refusal to distribute uninfected H9 cell lines unless others entered into collaborative agreements:

> Against the backdrop of comments from Gallo about the need for speed to counteract the growing AIDS epidemic, we note that the Report states that Gallo refused to distribute uninfected H9 cells unless collaborative agreements had been secured from the other investigators. . . . We consider failure to distribute uninfected H9 cells freely after publication of the article by Popovic et al. to be essentially immoral in view of the growing seriousness of the AIDS epidemic.

Exhibit H-224.

As for NIH standards, the 1980 Report on Recommendations for Distribution of Substances and Living Organisms for Research explicitly states that "NIH should not be accused of conflict of interest in determining what research is done,"[46]. A subsequent NIH policy regarding the distribution[47] of reagents noted the impropriety of NIH researchers' withholding unique materials

---

[45]Among the witnesses that will present such testimony are Drs. Schaffer, Sodroski, Wolf, Richards, Goldberger, Huth and Levine. See also, Exhibit H-74 reflecting the Pasteur researchers' acknowledgement that cell lines should be shared after publication; Exhibit H-5 showing the LTCB policy was to make materials available after publication.

[46] This policy was also reflected in the NIH Guide for Contracts and Grants (1988, 1991).

[47] See 1980 Report on Recommendations for Distribution of Substances and Living Organisms for Research.

developed with federal funds and acknowledged that "NIH should not be accused of conflict of interest in determining what research is done."[48] The 1988 NIH Guide for Contracts and Grants[49] explicitly stated:

> Restricted availability of unique resources upon which further studies are dependent can impede the advancement of research and the delivery of medical care. Therefore, when these resources are developed with PHS funds and the associated research findings have been published or after they have been provided to NIH under contract, they should be made readily available for research purposes to the scientific community. This policy applies to NIH intramural research as well as extramural research funded by grants, cooperative agreements, and contracts.

This principle is so universal that many journals require a scientist to make the cell line available as a condition of publishing the results of that research in the journal. Science, the journal in which the quatrain of HIV papers was published, specifically stated in its 1984 Information for Contributors that cell lines must be made available.[50] These requirements also appear in Science's 1993 Information for Contributors. Exhibit H-268. ORI believes that, as both a frequent contributor and reviewer for Science, Dr. Gallo knew or should have known of this

---

[48]Dr. Goldberger will testify about implementation of this policy.

[49] NIH Guide for Contracts and Grants 17(29):1, September 16, 1988. See also, Memorandum, Director, NIH to Robert Gallo, June 21, 1991.

[50] Exhibit H-267 states: "When a paper is accepted for publication in Science it is understood by the editors that any new cell line, virus strain, or monoclonal antibody described or used as a reagent in the experiments reported, or any sample on which the conclusions of the paper depend, will be made available to other bona fide scientists for further experimentation."

Science policy. Furthermore, the standard within the scientific community that materials should be made available to other researchers on publication was and is explicitly stated in the information for contributors for several of the journals on which Dr. Gallo served as an editor.[51]

C. Significance of Gallo's Deviations from These Standards:

Dr. Gallo's actions were a significant hindrance to progress in AIDS research, particularly within the PHS. Dr. James Mason, formerly Director of the CDC and former Assistant Secretary for Health, will testify that so egregious was Dr. Gallo's refusal to provide his reagents to CDC scientists who had requested them that he was forced to intercede on behalf of CDC researchers whose requests for the cell line and other reagents had not been honored by Dr. Gallo. Dr. Gallo's refusal to provide the cell line, and his provision of the cell line only after substantial delay and with significant conditions, was intentional. ORI witnesses will testify that Dr. Gallo informed CDC staff that the

---

[51] See, e.g., The Journal of Immunology ("The policy of the AAI in regard to the acceptability of manuscripts for publication is based on the principle that published results are verifiable. Authors are therefor expected to respect this principle by providing unique materials to qualified investigators." Exhibit H-293 (Dec. 1983); See also Cancer Research "Instructions for Authors." ("It is understood that by publishing any work in Cancer Research the authors agree to make freely available to other academic researchers any of the cells, clones of cells or DNA or antibodies, etc., that were used in the research reported and that may not be available from commercial suppliers.") Dr. Huth will provide testimony on journal policies requiring that materials be made available for replication of research results.

LTCB intended to delay sharing of the reagents until Dr. Gallo felt he had accomplished his own work with the reagents.[52]

Dr. Gallo's refusal to provide reagents and cell lines freely to qualified scientists who could further the cause of AIDS research belies Dr. Gallo's assertions that he rushed the four Science papers to publication because he was interested in saving lives. ORI witnesses will testify to Dr. Gallo's hubris in refusing to provide materials to CDC, despite repeated assurances from CDC that CDC's mission was disease prevention and control and not research competition with Dr. Gallo.[53] The CDC's difficulty in obtaining any materials from Dr. Gallo and Dr. Gallo's concern for his own glorification over concern for public health is reflected in Exhibit H-97. This exhibit also reflects the revulsion of scientists that Dr. Gallo would place such a restriction on the CDC in the face of a public health epidemic.

Dr. Gallo's conduct was so antithetical to the mission of PHS and standards within the scientific community that, at a June 18, 1984 NIH AIDS Executive Committee Meeting, Dr. Wyngaarden specifically ordered Dr. Gallo to provide the uninfected cell line to Drs. Malcolm Martin and Dr. Walter Dowdle. Exhibits H-99, H-103. CDC received the uninfected cell line on June 20,

---

[52] Among the witnesses providing testimony on these points are Dr. Curran, Dr. Murphy, Dr. Mason, Dr. Francis, Dr. Cabradilla and Dr. Kaly.

[53] Dr. Murphy will testify concerning the CDC's explicit and direct statements to Dr. Gallo that the CDC was interested solely in prevention and control of the pandemic.

1984. Exhibit H-101. On June 22, 1984, in response to a request for large amounts of the purified virus from CDC, Dr. Gallo responded that honoring the request would be difficult because of competing commercial interests. Exhibit H-101. Nevertheless, around the same time, Dr. Wyngaarden stated that the uninfected cell lines are being given to federal agencies as needed. Exhibit H-106.

Numerous witnesses will testify that Dr. Gallo's prohibition against other researchers who were provided the cell lines and reagents could not conduct comparisons of HTLV-IIIB with LAV was a restriction imposed by Dr. Gallo and not PHS.[54] ORI will present testimony that these restrictions were unprecedented and contrary to accepted PHS practices, and contrary to accepted practices for the conduct of research.[55]

Dr. Gallo's restrictions on providing HIV reagents to the extramural community was noted by many members in the scientific community. Exhibit H-175. For example, the Dean for Academic Affairs for the Harvard School of Public Health noted the agreement "places unacceptable restrictions on research, is

---

[54] Dr. Mason and Dr. Curran will provide testimony on this issue.

[55] Dr. Mason will testify regarding the impropriety of the restrictions on a material necessary for research on a vital public health issue. Dr. Berge Hampar will also testify that the restriction precluding comparison of the various putative AIDS isolates was extremely unusual. Drs. Martin, Schaffer, Francis and Cabradilla also will provide relevant testimony.

inconsistent with long-standing policies of this and many other major research institutions and threatens to inhibit vital research activity on a major threat to public health." Exhibit H-150. In response to this observation, Dr. Fischinger acknowledged that it would be "totally inappropriate" if there were any real strictures to the dissemination of research results in AIDS to other scientists and the public[56]. Exhibit H-151.

4. Summary

Dr. Gallo's refusal to identify the probable source of the HT cell line, coupled with his refusal to provide the uninfected cell line to qualified researchers, based on personal animosity or professional rivalry, and the restrictions that he placed on those who received the cell line or reagents constitute a serious deviation from accepted practices within the scientific community and thus, constitute scientific misconduct.

In addition to the witnesses identified above, Drs. Goldberger, Rall, Raub, Morgan and McGinnis will testify to the accepted norms of scientific practice for identification of unique cell lines and their availability to the scientific community and Dr. Gallo's deviation therefrom.

E. Allegation 8: Dr. Gallo Falsified the Role of LAV in the LTCB

---

[56] Dr. Fischinger acknowledged that any restriction on the dissemination of research results "would be unacceptably restrictive and not in keeping with either federal or university policies." Exhibit H-151.

The following statement appearing in the Popovic paper (Science 224: 497-500 (1984); Exhibit H-81) is false because LAV had been grown in the LTCB and was instrumental in Dr. Gallo's research findings:

> These findings suggest that HTLV-III and LAV may be different. However, it is possible that this is due to insufficient characterization of LAV because the virus has not been transmitted to a permanently growing cell line for true isolation and therefore has been difficult to obtain in quantity.

1. Summary of the Offer of Proof

Dr. Gallo is charged by ORI with falsely reporting that LAV had not been transmitted to a permanent cell line. Exhibit H-233. ORI will demonstrate that this sentence is embedded in a significant passage of the paper that is crafted in such a way as to be patently misleading. ORI will prove that this misrepresentation was material to the findings of the paper and was perpetrated in an attempt to distinguish falsely the LTCB's discoveries and to place the research of the LTCB inappropriately ahead of its perceived competitors. ORI will prove that Dr. Gallo personally penned the false statement at issue and that he knew or should have known of its falsity. When the LAV statement is read in context of the four papers published by the LTCB in Science on May 4, 1984 and with Dr. Gallo's statements and conduct with respect to the LAV virus and the efforts of the Pasteur, it is clear that the statement is not only false but is part of a pattern of conduct on Dr. Gallo's part to misrepresent, suppress and distort data and their interpretation. Exhibits H-

224, 226. Accordingly, ORI will show that Dr. Gallo's acts constitute scientific misconduct.

In presenting the evidence on this issue, ORI will show that the statement that LAV "has not been transmitted to a permanently growing cell line," on its face, is false. Moreover, ORI will present extrinsic evidence to put the sentence into its proper context and demonstrate the falsity of the statement. To this end, ORI will present evidence regarding the immediate context of the statement in the paper; how the statement evolved over the successive drafts of the paper; the LTCB work with LAV and other isolates; the relationship of LAV to HTLV-III; and whether LAV was the cause of AIDS; events occurring shortly before the final version of the statement was written, events that provided Dr. Gallo with a motive for the false statement; other statements by Dr. Gallo that similarly misrepresent the growth of LAV; and other actions by Dr. Gallo, outlined in allegations A1-A4 of this Offer, which are consistent with an intention to hide the LTCB use of LAV.

2. Standards for Scientific Reporting in 1983-84

The standards for scientific reporting in 1983-84, as now, require that, in publishing the results of their research, scientists fully and accurately describe the methods and techniques used in conducting the research and give full and proper credit to other scientists whose research, findings, or materials made an important contribution to the reported research. The standards also demonstrate that a scientist in Dr.

Gallo's position, i.e., who was the Laboratory Chief, senior author of the paper and author of the challenged statement concerning LAV has an obligation to ensure the accuracy of the statement. Therefore, he is held accountable for scientific misconduct either because of intentional falsification or because he should have known it was false.

3. LAV Was Grown in LTCB Before the *Science* Paper Was Submitted

ORI will demonstrate that members of Dr. Gallo's laboratory had grown LAV in a permanent cell line before the Popovic paper was submitted to Science on March 30, 1984. Exhibits H-28, 29, 32. On October 21, 1983, acting pursuant to Dr. Popovic's instructions of October 20, 1983, Betsy Read attempted to infect various permanent T-cell lines with LAV.[57] These cultures were started and left to Ms. Read's care because Dr. Popovic had left the country. (Ms. Read Notebook 1 at 222, 223; Exhibit H-325). Specifically, Ms. Read infected HUT-78, Ti7.4, SR2, CL7, and HOS with LAV. On October 24, 1983, Ms. Read listed those LAV cells as being in culture. Ms. Read sent the LAV cultures to Dr. Prem Sarin's laboratory for RT analysis on October 27, 1983, with positive reverse transcriptase results identified for several of the LAV cell lines on November 9, 1983. (P. Sarin Notebook at

---

[57] The LAV sample used was designated MKT-LAV when the LTCB received it in September 1983. Another LAV sample, designated JBB/LAV, accompanied the MTK-LAV sample. Exhibit H-29. Both MTK-LAV and JBB/LAV purportedly came from the patient "BRU."

25-26; Exhibit H-336) and Gallo Submission to OSI (May 15, 1990), Att. LAV 16.

When Dr. Popovic returned around the first of November, 1983, Ms. Read delivered to him the three surviving LAV cell lines. (M. Popovic Notebook at 29; Exhibit H-323). Betsy Read testimony. On November 8, 1993, Dr. Popovic identified those three cell lines simply as HOS, Ti7.4 and HUT-78. (M. Popovic Notebook at 29, 32; Exhibit H-323). The LAV cell lines were tracked by Dr. Popovic for several weeks, with periodic entries

indicating their continued viability[58] (M. Popovic Notebook at

---

[58] ORI will demonstrate that the LTCB's work with the LAV cell line continued over several months. ORI will show, through the laboratory notebooks, that the LTCB's work with the MOV cell line was part of the LTCB's efforts with LAV. Exhibit H-47. The evidence reveals that MOV is simply LAV, renamed. Drs. Gallo and Popovic argue that the "MOV" cell lines were infected with a different isolate from the LAV cell lines, an isolate identified at the LTCB. However, this assertion cannot be substantiated and, in fact, is contradicted by the available evidence. Specifically, the evidence for this assertion includes the following:

(1) Dr. Popovic directed Ms. Read to attempt infections of permanent T-cell lines using LAV on October 20, 1983. (M. Popovic Notebook at 27). Ms. Read's notes show that on October 21, 1983 she infected five T-cell lines with LAV. (E. Read-Connole Notebook 1 at 222). There are no other records of any simultaneous infections of these cell lines with any other isolates.

(2) Ms. Read's notes show the five LAV cell lines "in culture" on October 24, 1983. (E. Read-Connole Notebook 1 at 223). There are no other cultures of this collection of cell lines noted in the LTCB records.

(3) Ms. Read's testified to OSI that she delivered those surviving LAV cell lines (HOS, HUT-78, Ti7.4) to Popovic during the first week of November, 1983, upon his return to the LTCB from Basel. She specifically stated that the HOS/LAV cell line was in "bad shape" when she transferred it to Popovic.

(4) Dr. Popovic's notes for November 8, 1983 list these three cell lines (HOS, HUT-78, Ti7.4) and show that they are infected, although the virus isolate is not identified. (M. Popovic book at 29) Notably, the "HOS" culture is designated "dead cells," corresponding to Read-Connole's testimony about the poor quality of this culture. Later, Dr. Popovic would tell OSI that his November 8, 1983 notebook entry reflects the cell lines he will later designate as "MOV." (March 1991 Submission at 36-37). However, there are no records showing anything other than LAV was ever used to infect those three cell lines prior to, or on, November 8, 1983.

(5) Ersell Richardson transmitted samples HUT-78/LAV and Ti7.4/LAV to Matthew Gonda for electron microscopy ("EM") on or about November 15, 1983. Exhibit H-37B. Dr. Gonda reported the EM results on December 14, 1983 on both infections as follows: "Positive; lentivirus. Productive lentivirus infection with all

29, 32, 33, 34, 37, 40, 43, 44; Exhibit H-323).

The evidence will clearly demonstrate that Dr. Popovic had transmitted LAV into a permanent cell line. Dr. Popovic admitted this fact to OSI when he also indicated that LAV grew very well. Exhibit H-319. Moreover, the evidence will show that, by December 1983, in addition to Dr. Popovic, Ms. Read knew that LAV had been grown in a permanent cell line no later than mid-January 1984.[59] Dr. Gallo was informed that LAV was grown in a permanent cell line. Sometime after receiving this information Dr. Gallo purportedly ordered Dr. Popovic to stop working with LAV and concentrate on the LTCB's isolates.[60]

4. LTCB Kept Growth of LAV Secret

---

forms of virus maturation." When Dr. Gonda's letter was released under the FOIA in 1986, the LAV statements were mysteriously redacted. Exhibit H-37A.

(6) On December 14, 1983, IFA's were performed. Two LAV cell lines (HUT-78/LAV; Ti7.4/LAV) were positive when tested against serum from patient "BRU." (E. Read-Connole Notebook 1 at 171) There are no IFA data for any sample identified as "MOV."

(7) Roche Diagnostics analyzed a sample of MOV dating from March 1984 and confirmed that it is LAV/LAI. The letter to Nature reporting the Roche results stated that "the possibility of contamination or replacement of the MOV culture with HIV-1 from M2T-1B or an HIV-1 Lai/IIIB containing cultures cannot be ruled out." (Exhibits H-195-96, 198, 213, 215, 217,220, 231).

[59] M. Popovic (12/1/90) at 44 (Exhibit H-320).

[60] M. Popovic (6/26/90) at 123-24, 146 (Exhibit H-319); M. Popovic (12/1/90) at 38; Gallo (12/2/90) at 61 (Exhibit H-314), "[A]lmost as soon as I learned about [Popovic's] transient growth of LAV in a cell line at the end of December 1983, at some time in early '84 or January, maybe a week, maybe two, I am telling him forget everything with LAV, concentrate on our own isolates;". R. Gallo (12/2/90) at 188. Exhibit H-314.

Growth of the LAV virus will further be evidenced by a telephone conversation in late November/early December 1983 between Dr. Luc Montagnier of the Pasteur and Dr. Popovic. Dr. Popovic indicated that he knew "how to handle" LAV.[61] However, believing that it was the LTCB's prerogative to publish their results first and inform the French later, Dr. Popovic consciously decided not to volunteer to Dr. Montagnier that the LTCB had transmitted LAV to a permanent cell line.[62] Indeed, ORI will show that this admission is significant in that it is one of many indications of the LTCB's efforts to conceal their work with LAV, efforts that ORI will show culminated in the falsification of the sentence at issue. Testimony of Dr. Montagnier.

This underlying current of secrecy again surfaced in February 1984, when Dr. Chermann of the Pasteur questioned Dr. Popovic about the LTCB's use of LAV. In that conversation Dr. Popovic again declined to inform the French that he had transmitted LAV to a permanent cell line and stated that only Dr.

---

[61] R. Gallo (8/3/90) at 102 (Exhibit H-311); Letter from L. Montagnier to S. Hadley (6/18/91) (Exhibit H-213); M. Popovic (6/26/90) at 112 ("In the end of November '83, I again called him [Gallo] up at his home, and I told him: We got it, we learned how to handle the virus.") Exhibit H-319.

[62] Letter from L. Montagnier to S. Hadley (6/18/91), Exhibit H-213; M. Popovic (6/26/90) at 112-13, Exhibit H-319.

Gallo could answer questions about the LTCB's use of LAV.[63] See also, Exhibits H-98 and H-143.

5. Dr. Gallo Knew LAV was Growing in LTCB

The evidence will clearly reveal that the LTCB had grown the LAV virus in a permanent cell line prior to January 1984.[64] Additionally, Dr. Gallo clearly knew of this growth prior to publication of the Science papers in May 1984. Exhibit H-66. It is equally clear that the LTCB was refusing to share that information. See, e.g. Exhibit H-60. Moreover, the evidence will show that not only did Dr. Gallo know that his own Lab had LAV in a permanent cell line, but he also had reason to believe that Pasteur also had such growth. Prior to publication of the at-issue Science paper, Dr. Gallo acknowledged that he was aware the Pasteur scientists had LAV in a cell line. See Gallo press conference of April 23, 1984, at 31. See also S. Wain-Hobson et

---

[63] See Letter from J. C. Chermann to R. Gallo (7/11/84) stating: "[W]hen I asked Dr. M. Popovic if he had succeeded in growing LAV in your laboratory, the answer was, 'I cannot speak, only the boss can speak'!"(Exhibit H-112). Compare Letter from R. Gallo to J.C. Chermann (8/24/84) at 2, stating: "[Mika] said the question about LAV was never asked of him by you." (Exhibit H-120). But see also M. Popovic (6/26/90) at 76 where Popovic states that, when he saw Chermann in February 1984, he did not want to talk to him because he realized that the French did not have a system. Dr. Popovic states that he said "bosses can talk," and walked away. Exhibit H-319, Testimony of Dr. Chermann.

[64] Questions regarding whether LAV had been placed in a permanent cell line are further proof to rest by the fact that the EM pictures purported to be HTLV III in the Science paper were actually LAV. Such pictures are of a clarity that demonstrates they came from a well-established culture of growth. H-162, 163, 164, 65, 166, 292; Martin, Chermann, Schaffer, McGrath, and Cabradilla will testify on this point.).

al., Science May, 1991 (demonstrating that the Pasteur scientists were producing LAV in an EBV-transformed lymphoblastoid cell line) (Exhibits 211, 213); Drs. Martin, Cabradilla, Francis, McGrath, Chermann, Montagnier, Barré-Sinoussi, Schaffer and Hadley will testify about the growth of LAV in the Pasteur, the CDC, and the LTCB and Dr. Gallo's awareness of this growth.

The evidence will also show that RT, IFA and EM analyses were performed on the LAV cell lines and showed positive results. Id. (P. Sarin Notebook at 25-26 (Exhibit H-336); E. Read Notebook 1, at 191 (Exhibit H-325); Exhibit H-37; See also Letter from M. Gonda to M. Popovic (Dec. 14, 1983) reporting "productive lentivirus infection with all forms of virus maturation." Thus, ORI will demonstrate that, not only had the LTCB transmitted LAV to a permanent cell line prior to publication of the Science paper, but the LAV virus had also been significantly characterized in several other laboratories, including the Pasteur, CDC, and the LTCB, prior to publication of that paper. Indeed, the Pasteur scientists made a number of scientific presentations (with Dr. Gallo present) and published several papers describing their characterization of LAV. See e.g., Cold Spring Harbor presentation (Sept. 15, 1983) (paper handed by Dr. Montagnier to Dr. Gallo at this time); thus Dr. Gallo clearly had knowledge of this characterization. Exhibits H-27, 34; New York Academy of Sciences presentation (Nov. 14, 1983) (showing effect of LAV on T-Cells and showing "Characteristics" of LAV in table 4); Park City, Utah, presentation by J.C. Chermann (at

which Dr. Gallo was moderator) (Feb. 6, 1984) of "Characterization and Possible Role in AIDS of A New Human T-Lymphomatic Retrovirus", Exhibits H-44, 44A; "Isolation of New Lymphotropic Retrovirus from Two Siblings with Hemophilia B, One with AIDS", Vilner et al., the Lancet at 753 (April 7, 1984); "A New Type of Retrovirus...", L. Montagnier et al., Annals of Virology, Vol. 135 E, at 119, (April, 1984) (describing the Pasteur's "Further Characterization of LAV"); Characterization of the RNA Dependent DNA Polymerase of a New Human T Lymphotropic Retrovirus, Re. et al., Biochemical and Biophysical Research Communications, Vol. 151, No. 1, at 126 (May 31, 1984) (presented at Park City, Utah Feb. 5-10, 1984). See also, Bal. Acad. Nat. Med., February 28, 1984; Montagnier Presentation, October 1, 1983.

Similarly, ORI will show that contrary to Dr. Gallo's assertion in the Science paper, LAV had not been difficult to obtain in quantity. Indeed, the record will show that the Pasteur scientists produced the LAV virus in substantial quantities and supplied the LTCB with ample quantities of LAV upon demand prior to May 1984. See, e.g., Dr. Gallo's OSI submission (May 15, 1990), Att. LAV-6 ; Testimony of Drs. Chermann, Barré-Sinoussi, Montagnier, Francis and Martin. Moreover, the evidence shows that Dr. Gallo was fully aware of the fact that the LTCB clearly grew LAV and had the ability to

produce it in large quantities had they so desired. Exhibit H-37.[65]

6. The LAV Statement was Deliberately Misleading

ORI will show that the full text of the at-issue section of the paper is penned in a manner that is clearly misleading to the reader. The paragraph states that LAV and HTLV-III may be different. However, this difference is said to be potentially caused by "the insufficient characterization of LAV because the virus has not been transmitted to a permanently growing cell line....."[66] (emphasis supplied). This statement, too, is patently false and misleading. First, ORI will demonstrate that Dr. Gallo was aware that the LTCB had transmitted LAV to a permanent cell line.

Further, ORI will show both that growth in a permanent cell line is not a necessary requisite for characterization and also that LAV had been substantially characterized by the LTCB through

---

[65] The evidence will clearly show that "LAV" identified as LAV in the LTCB notebooks was readily obtainable in quantity. Accordingly, the at-issue statement in the Science paper penned by Dr. Gallo is patently false. Moreover, ORI will show that the isolate identified as MOV was LAV. See Discussion. The LTCB had this renamed version of LAV mass produced. Indeed, Dr. Sarngadharan used the LAV/MOV virus for numerous experiments including substantial protein chemistry work (Gallo OSI submission (May 10, 1990), Att. MOV-5); development of the hyperimmune rabbit antiserum, which was the first HIV-specific reagent (Gallo OSI Submission May 16, 1990); and development and large-scale use of an HIV-antibody ELISA. Id.

[66] ORI will show that, even after the similarities of LAV and HTLV III were known, Dr.Gallo continued to obfuscate the similarities of these isolates in an effort to advance his claims to priority and primacy. See e.g. Exhibits H-140, 141.

CPE, EM, IFA and RT analyses. Given the information Dr. Gallo had of these developments with LAV by May 1984, his statement in the Popovic statement is both fallacious and clearly misleading. Exhibits H-36, 39, 43, 45, 46, 71, 86.

ORI will also demonstrate that Dr. Gallo's suggestion, in the quoted phrase, that LAV was "difficult to obtain in quantity" is similarly untrue and misleading. First, because the LTCB scientists had transmitted LAV to a permanent cell line in 1983, they clearly could and did obtain LAV in quantity. Dr. Gonda's report of positive EM's of the LAV cell lines described them as "productive lentivirus" with all forms of virus maturation. Letter from M. Gonda to M. Popovic (Dec. 14, 1983) Exhibit H-37. Second, growth in a permanent cell line is not a prerequisite to obtaining the virus in quantity. The evidence reveals that, in 1983 and 1984, the Pasteur was growing LAV in an EBV-transformed lymphoblastoid cell line. S. Wain-Hobson et al., supra; testimony of J.C. Chermann. Third, during a scientific meeting at Cold Spring Harbor in September 1983, Dr. Luc Montagnier told Dr. Popovic that LAV was "a high producer." Fourth, the Pasteur had freely supplied the LTCB with sufficient amounts of LAV virus when requested. See e.g. Exhibits H-28, 29. Thus, Dr. Gallo knew or should have known that his statement with respect to the ease with which LAV could be obtained in "quantity" was false.

Accordingly, ORI will establish that the statements in the Science paper by Dr. Gallo that LAV had been insufficiently characterized, had not been transmitted to a permanent cell line,

and had been difficult to obtain in quantity are misleading and false. Indeed, ORI will show that Dr. Gallo knew these statements were misleading and false when he inserted them into the paper. Therefore, his actions constitute scientific misconduct.[67]

7. Drafts of the *Science* Paper Show Intent to Hide Role of LAV

ORI will demonstrate both the falsity of the challenged passage in the Science paper and Dr. Gallo's awareness of its falsity through an analysis of the drafts of the Science paper. Exhibits H-48 through H-56, H-72, H-81. ORI recognizes that the disputed statement does not appear in the handwritten draft preceding the published version; thus, it is impossible to determine definitively the author. However, Dr. Popovic denies writing the statement (Transcript of M. Popovic (Dec. 1, 1990) at 90, Exhibit H-320; See also Transcript of M. Popovic (Apr. 10, 1991) at 9-10, Exhibit H-322) and Dr. Gallo has admitted to being the principal draftsman of this section of the Popovic paper. Most importantly, Dr. Gallo has admitted that he wrote the

---

[67] As noted throughout this Memorandum, although ORI will demonstrate that Dr. Gallo knew the statement was false when he penned it, ORI need not necessarily prove actual knowledge to prove scientific misconduct. Rather, ORI will, alternatively, demonstrate that Dr. Gallo penned the false statement, knew the statement was in the published text, was the senior author on the paper, was the Laboratory Chief in charge of the research reported in the paper and had an affirmative obligation to know whether the statement he inserted into the paper was false. Violating this obligation constitutes scientific misconduct. Testimony of Drs. Goldberger, Huth, Morgan, Martin, Francis, Rall, Richards, Schaffer and Woolf.

challenged discussion in each of the drafts of the Popovic paper and he has assumed responsibility for the disputed statement. (Transcript of R. Gallo, Dec. 2, 1990) at 59, 61, Exhibit H-314).[68]

ORI will establish that Dr. Popovic strongly disagreed with Dr. Gallo's decision to exclude his LAV data from the Popovic paper and his references to the LTCB's growth of LAV in a permanent cell line.[69] In fact, the evidence will show that Dr. Popovic was so concerned by Dr. Gallo's decision to delete the acknowledgement of the role of the Pasteur virus in the LTCB research, that he removed drafts of the paper from the LTCB and gave them to his sister in Austria so that he could later prove, if necessary, that he had given appropriate credit to the French

---

[68] Although Dr. Gallo has accepted responsibility for this provision, in the event he should now argue that he should not be held accountable for this language, ORI will demonstrate that, because Dr. Gallo was clearly responsible for this section, was the Laboratory Chief responsible for reviewing the work and was the senior author on the paper, he knew or should have known that the statement was false and his actions amount to scientific misconduct.

[69] See Letter from M. Popovic to S. Hadley of (May 15, 1991) at 7-8, Exhibit H-208 ("I did not agree with Dr. Gallo that the references to the work we did with the French virus should be omitted or even significantly minimized.... I thought it was wrong not to credit Dr. Montagnier's group's contributions more clearly."); see also Transcript of M. Popovic (Apr 10, 1991) at 6-7, 32, Exhibit H-322 ("I mentioned several times that this paper would be valued far more if LAV would be in."); Transcript of M. Popovic (June 26, 1990) at 112-13, Exhibit H-319; Transcript of M. Popovic (Dec. 1, 1990) at 103-05, Exhibit H-320 ("I think I was right because this my paper is suspicious because those LAV data are not included....It was Gallo's decision to include the LAV data in a later paper with the French."); Transcript of M. Popovic, Dec. 1, 1990 at 155-58.

in his drafts of the paper.[70] Even in the face of this extraordinary event, Dr. Gallo maintains that Dr. Popovic merely had a brief discussion with him regarding the inclusion of the LAV data and its growth in a permanent cell line in the LTCB, and curiously fails to recall Dr. Popovic vigorously objecting to their exclusion.[71]

The drafts of the Popovic paper are highly instructive with respect to the nature and intent of Dr. Gallo's actions in writing the disputed paragraph. Exhibits H-48-56, H-72. All available drafts, including those drafts that Dr. Popovic retrieved from his sister in Austria, will be submitted as evidence.[72] The various drafts of the Popovic paper will be introduced to reflect the evolution of the controversial

---

[70] See Letter from M. Popovic to S. Hadley of (May 15, 1991) at 7 (Exhibit H-208), stating that he took the unusual step of giving drafts of the papers to his sister "because I believed that sometime in the future, I might need them as evidence to prove that I gave fair credit to Dr. Montagnier's group." See also Popovic, April 10, 1991 at 7-8, where Dr. Popovic states he gave the drafts to his sister because he thought LAV should have been in the paper and he was moving and wanted to ensure the drafts' safety. Id. at 35-36. Dr. Popovic subsequently retrieved these drafts from his sister and provided them to OSI.

[71] Transcript of (Dec. 2, 1990) R. Gallo at 186, Exhibit H-314 ("I do remember a very brief discussion about it; yes. And it was -- there wasn't much emphasis. I think, Mika thought maybe we should make a statement to the effect that LAV was in culture. If Mika -- don't think that Mika argued forcefully or strongly that we have to have some data on LAV growing in the culture, that is not the case. He did mention it in an almost casual way, maybe we should put a statement that LAV is growing in culture or that we have succeeded in that at least for the time being with partial characterization.")

[72] See supra, re Dr. Gallo's responsibility for discussion maintaining these drafts.

statement. The drafts reveal a steady diminution in the attribution afforded the Pasteur and the role of LAV in the LTCB's AIDS research. The successive drafts reveal Dr. Gallo's apparent increasing determination to exclude references to LAV, a determination that eventually culminated in the false and misleading statement regarding LAV selected by Dr. Gallo for the final version of the paper. The ORI's focus will largely begin with draft 2, a version typed from Dr. Popovic's handwritten version 1. In this draft, LAV's importance in the development of a permanent cell line and LAV's origin are identified clearly by Dr. Popovic. Draft 2 states in relevant part:

> Several in vitro established permanent cell lines originated from human malignancies were assayed for susceptibility to infection with cytopathic variants of HTLV. LAV as a reference virus (gift from Dr. L. Montagnier) has been used in the first series of experiments. Two cell lines with characteristics of mature T-cells showed a susceptibility to the virus infection as determined by reverse transcriptase (RT) assay.... The infected parental cell line exhibited positivity for particulate reverse transcriptase activity in culture fluids and about 20% of the infected cell population were positive in indirect immune fluorescent assay (IFA) using a serum from a hemophiliac patient called E.T. with lymphadenopathy.

Version 2 at 3. Exhibit H-49.

Draft 3 is substantially the same as version 2. Compare Exhibits H-49 and H-50.

Draft 4 reflects substantial changes by Dr. Gallo. Significantly, Dr. Gallo struck through the referenced statement above acknowledging the use of LAV in Dr. Popovic's cell line experiments. Dr. Gallo's handwritten note beside the deletion of

the references to LAV states: **"Mika, you are crazy."** Exhibit H-51 at 5. (Emphasis added). Similarly, Dr. Gallo deleted a statement by Dr. Popovic that LAV "... is described here as HTLV-III."[73] Next to this statement Dr. Gallo wrote to Dr. Popovic in the margin **"I just don't believe it. You are absolutely incredible."** Exhibit H-51 at 3 (emphasis supplied). Once Dr. Gallo had eliminated the acknowledgement of the use of LAV as the focus of the initial experiments, he added a passage substituting HTLV-III as the focus of the paper. Dr. Gallo wrote; "[H]ere we report development of a system for routine detection and isolation of... highly cytopathic HTLV variants in patients with AIDS and pre-AIDS. The majority of the new isolates belong to a subgroup which we call HTLV-III." Exhibit H-51 at 3.

Additionally, Dr. Gallo fundamentally altered the description of Dr. Popovic's initial LAV experiments. These first experiments were actually conducted using two cell lines (Ti7.4 and HUT78). However, Dr. Gallo changed the description to a single cell line. In order to obscure the cell lines further, Dr. Gallo altered the identifying information on this cell line from a patient with Sezary Syndrome, an identifier that would likely clue the reader that the "new" cell line was actually HUT-78, to a patient with ATL.

---

[73] This reference to HTLV-III as LAV was included in drafts 1, 2, and 3. Exhibits 48 at 1, 49 at 1, and 50 at 3.